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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,089	HARTLEY ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed October 22, 2008. Claims 1, 3-4, 7-9, 11-12, 14, 28 and 35-47 are pending. Claims 1, 3-4, 36, 40 & 41 have been amended. Claims 2, 5-6, 10, 13, 15-27 and 29-34 have been cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 3-4, 8-9, 12, 14, 36-37, 40-44 & 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (US 5,421, 349) in view of Radisch, Jr. (US 5,295,493), Stevens et al. (US 5,584,803), and further in view of Chaisson et al. (US 6,086,548).

In regards to **claims 1, 36 & 41**, Rodriguez et al. disclose a guide wire 10, the guide wire 10 having 5 zones of varying stiffness comprising:

a mandrel 11;

a proximal zone 22 of transition from high stiffness to semi-stiffness and having a length of about 3 cm;

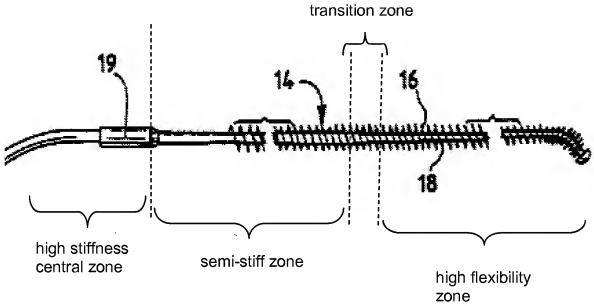
an elongate central zone 11 of high stiffness and substantially constant diameter along its length;

a tapered distal zone 14 of transition from high stiffness to being relatively flexible and wherein the distal zone 14 is subdivided three zones (see drawing below):

a semi stiff zone adjacent to the central zone;

a transition zone having flexibility of from semi-stiff extending to flexible; and,

a tip zone having flexibility;



wherein the proximal zone 22 comprises a proximal wire coil 30 of substantially constant diameter and the distal zone 14 comprises a distal wire coil 18 of substantially constant diameter (see figs. 1-2; col. 2, lines 19-20, 27-31, 42-44 & 66-68; col. 3, lines 26-29 & 41-44; see claims 1 & 4 of Rodriguez).

In regards to **claim 4**, Rodriguez et al. disclose a guide wire 10 wherein the proximal zone 22 comprises a tapered mandrel with a proximal wire coil 30 of substantially constant coil diameter on and extending along the tapered mandrel (see fig. 2).

In regards to **claim 8**, Rodriguez et al. disclose a guide wire 10 wherein the proximal wire coil 30 terminates in a rounded tip 32 (see fig. 2; col. 3, lines 36-41).

In regards to **claim 9**, Rodriguez et al. disclose a guide wire 10 wherein the distal zone 14 comprises in order from the central zone 11, a tapered mandrel portion and a portion16 of constant reduced diameter with a distal wire coil 18 of substantially constant coil diameter on and extending along the tapered mandrel portion and the portion 16 of constant reduced diameter (see fig. 1).

In regards to **claims 12 & 46**, Rodriguez et al. disclose a guide wire 10 wherein the distal wire coil 18 terminates in a rounded tip (see fig. 1).

In regards to **claim 37**, Rodriguez et al. disclose a guide wire 10 wherein the diameter of the mandrel in the central zone, the coil diameter of the proximal wire coil and the coil diameter of the distal wire coil are of substantially equal (see fig. 1).

In regards to **claim 44**, Rodriguez et al. disclose a guide wire 10 having a transition from full stiffness to semi-stiff at the proximal end, the semi-stiff proximal portion providing flexibility to allow the interventional delivery system to be loaded onto the wire 10 and advanced without becoming jammed in the interior of the device (see figs. 1-2).

Rodriguez et al. teach a guide wire, as described above, that fails to explicitly teach a distal zone having a distal pre-formed curve with a radius of curvature of from 5 cm to 15 cm or J-tip zone with a radius of curvature of from 5 to 20 mm.

However, **Radisch, Jr.** teaches that it is known to provide an endovascular guidewire with a distal zone having a distal pre-formed curve (22, 30, 40, 30a) with a

radius such that the guide wire may correspond in shape to an arterial path through the aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery; wherein the central zone comprises a stainless steel mandrel (see abstract; see figs. 1-1A, 2-2A, 3-3A & 4-4A; col. 2, lines 52-68; col. 3, lines 1-6 & 24-28; col. 4, lines 15-22, 30-42 & 58-67; col. 5, lines 12-18 & 33-45).

Moreover, **Stevens et al.** teach that it is known to provide endovascular devices with a distal pre-formed U-shaped curve for insertion into a thoracic arch region of an aorta such that the distal curve defines a radius of curvature of about 5 cm to 8 cm so as to generally conform in shape to the aortic arch (see fig. 36a; see col. 8, lines 34-37 & 52-67; col. 9, lines 1-10, 15-20, 35-38 & 48-52; col. 41, lines 66-67; col. 42, lines 1-10).

Even moreover, **Chaisson et al.** teach that it is known to provide endovascular devices for insertion into a thoracic arch region of an aorta with a J-shaped distal tip having a radius of curvature of about 20 mm (see abstract; see figs. 5 & 9; col. 4, lines 35-37).

In regards to **claims 1, 14, 36 & 40-43**, since Radisch, Jr. teach that it is known to shape the distal zone of a guide wire to match an anatomical shape such that the guide wire may correspond in shape to an arterial path through the aorta to hold the guide wire in its prepositioned place through the aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left

circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery (see col. 2, lines 52-68; col. 3, lines 24-28), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guide wire of Rodriguez et al. to shape the distal zone into a pre-formed anatomical curve as taught by Radisch, Jr. so that the guide wire may correspond in shape to an arterial path to hold the guide wire in its prepositioned place through the aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery.

Moreover, both Radisch, Jr. and Stevens et al. teach endovascular devices having a distal pre-formed U-shaped curve for insertion into a thoracic arch region of an aorta to correspond to the curvature of a patient's aortic arch; since Stevens et al. further teach that it is known to provide said endovascular device with a radius of curvature of about 5 cm to 8 cm in order to position the distal end of the anatomical device in the ascending aorta when the anatomical device is disposed in the aortic arch (see col. 8, lines 59-67), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. above to include a distal pre-formed curve with a radius of curvature of from 5 cm to 8 cm as taught by Stevens et al. in order to position the distal end of the anatomical device in the ascending aorta when the anatomical device is disposed in the aortic arch.

Even moreover, it is known to provide endovascular guide wire devices with a J-shaped tip zone having a single direction of curvature to reduce the likelihood of trauma caused by the advancing guide wire (see fig. 1 & col. 6, lines 35-44 of US 6,254,550). Since Rodriguez et al. teach that the distal end 14 may be curved (see fig. 1; see col. 3, lines 7-8) and Chaisson et al. teach that it is known to provide endovascular devices for insertion into a thoracic arch region of an aorta with a U-shaped distal tip having a radius of curvature of about 20 mm (see abstract; see figs. 5 & 9; col. 4, lines 35-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. and Stevens et al., above, with a J-shaped tip zone having a single direction of curvature as is known in the art with a radius of curvature of 20 mm as taught by Chaisson et al. in order to reduce the likelihood of trauma caused by the advancing guide wire. Similarly, it has previously been held that merely changing size (i.e. the radius of curvature of a J-tip) is an obvious expedient--see *In re Rose, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955).*

In regards to **claim 3**, since Radisch, Jr. teaches that it is desirable to provide the the guide wire with a suitably strong material such as stainless so that the guide wire can be formed and maintained in the desired shape (see Radisch, Jr., col. 4, lines 18-22), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. and Stevens et al., above, with a stainless steel central portion as taught by Radisch, Jr. in order to provide a core wire of a suitably strong material that can be

formed and maintained in a desired shape. Moreover, stainless steel is a known biocompatible material.

4. **Claims 28, 35, 38-39, 45 & 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (' 349) in view of Radisch, Jr. ('493), Stevens et al. ('803), Chaisson et al. ('548), and further in view of Ferrera (US 6,165,140).

Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach a radiopaque guide wire or a polytetrafluoroethylene coated wire coil.

However, **Ferrera** discloses a guide wire comprising a radiopaque guide wire and a wire coil having a portion 40 coated with polytetrafluoroethylene (PTFE) (see col. 3, lines 42-48).

In regards to **claims 28, 39 & 47,** it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with a radiopaque coil as taught by Ferrera in order to increase the visibility of the guide wire under fluoroscopy.

In regards to **claims 35, 38 & 45,** it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with a PTFE coating as taught by Ferrera in order to improve the lubricity of the guide wire and fixedly maintain the wire coil in place.

5. **Claims 7 & 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (' 349) in view of Radisch, Jr. ('493), Stevens et al. ('803), Chaisson et al. ('548), and further in view of Clayman et al. (US 6,716,183).

Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach coils that are laser welded toe the mandrel portion.

However, **Clayman et al.** disclose(s) a guide wire to assist in anatomic deployment, the guide wire having: an elongate central zone 18 of high stiffness, and substantially constant diameter along its length; a proximal zone 21 of transition from high stiffness to semi-stiffness and having a length; and a tapered segmental distal zone 16 of transition from high stiffness to being relatively flexible; wherein the proximal zone 21 comprises a tapered mandrel with a proximal wire coil 41 of substantially constant coil diameter on and extending along the tapered mandrel; wherein the proximal wire coil is laser welded to the tapered mandrel (see fig. 7; column 6/lines 45-48); wherein the proximal wire coil terminates in a rounded tip 50 (see fig. 2).

Since Rodriguez et al. teach a wire coil that is epoxied (i.e. semi-permanent attachment) or soldered (i.e. permanent attachment) in order to attach the wire coil to the shaft (see col. 3, lines 45-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with

laser welded wire coil as taught by Clayman et al. in order to permanently attach the wire coil to the shaft.

Response to Arguments

6. Applicant's arguments filed October 22, 2008 have been fully considered but they are not persuasive. Applicant argues that Stevens teaches away from the use of a distal tip which can bump into the aortic valve without causing damage. Applicant argues that none the references teach a tip curve or the claimed zones of stiffness.

In response to the Applicant's argument that Stevens teaches away from the use of a distal tip which can bump into the aortic valve without causing damage, the Examiner respectfully traverses. First, the Examiner notes that Applicant's argument is completely unsubstantiated and the Examiner has been unable to verify the validity of said argument. Nonetheless, the Examiner observes that Applicant admits at page 2 of the Remarks that "Radisch and Chaisson are directed towards guide wires which are shaped to enter into other vessels, such as the right coronary artery or carotid artery *from the aortic arch region*" [Emphasis added]. As such, it is unquestionable that the guide wires of Radisch and Chaisson are first configured to access the aortic arch itself so as to be able to "enter into other vessels...from the aortic arch region" (see figs. 1, 2, 3 & 4 of Radisch and fig. 9 of Chaisson, which clearly show the devices of Radisch and Chaisson positioned in the aortic arch). Similarly, Stevens teaches a vascular device, which is configured to be positioned in the aortic arch (see col. 8, lines 59-67). As such, Radisch, Chaisson and Stevens, in fact, teach devices that are positionable in the aortic arch. As such, given the fact that Radisch, Chaisson and Stevens attempts to solve the

same problem of stably positioning an endovascular device on aortic arch, the Examiner submits that Radisch, Chaisson and Stevens in no way, shape or form teach away from each other.

In regards to the Applicant's contention that none the references teach a tip curve having a single direction of curvature, the Examiner respectfully traverses. First, the Examiner notes that Applicant has misconstrued the Examiner's prior Office action. However, for further clarity, the Examiner points out that J-tip shaped guidewires having a single direction of curvature are known in the art to reduce the likelihood of trauma caused by the advancing guide wire (see fig. 1 & col. 6, lines 35-44 of US 6,254,550). Moreover, Chaisson teaches a device having a U-shaped portion 30 with a radius of 20 mm and a free distal tip 31 that is perpendicular to the main longitudinal axis (see figs. 5 & 9; col. 4, lines 38-42). According to Chaisson, the free distal tip 31 serves the specific purpose of facilitating entry of the device into the right subclavian artery (see figs. 9-10; col. 4, lines 29-35). As such, providing a device with a distal portion as taught by Chaisson except for the omission of the free distal tip 31 achieves no patentably distinguishable device since it has previously been held that merely removing an element (i.e. the free distal tip 31) and its function (i.e. facilitating entry of the device into the right subclavian artery) is not patentable--See In *re Karlson, 311 F.2d 581, 583, 136 USPQ 184, 186 (CCPA 1963); In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).*

In regards to Applicant's argument that none the references teach the claimed zones of stiffness, the Examiner respectfully traverses. The Examiner notes that Rodriguez et al. teach a guidewire that comprising a proximal end, a central zone, and a

distal end (see col. 2, lines 3-11) wherein the flexibility of the distal end is greater than that that of the central zone and that of the proximal end; wherein the proximal end is of greater flexibility than that of central zone. The distal end of the guidewire of Rodriguez is tapered (see col. 2, lines 66-68) and includes "a range of diameters" that are less than the central zone portion (see col. 2, lines 12-18 & 66-68); wherein the distal end has a length that extends out to fifteen inches and more in many cases (see col. 2, lines 23-26). In other words, it is unquestionable that Rodriguez et al. teach a guidewire having a flexible tip and a range of diameters, each diameter corresponding to a zone of flexibility. As can be seen in the depiction supra, Rodriguez et al. disclose a distal end portion that includes at least 3 zones of different diameters, each inherently including a different flexibility by reason of their different diameters (see fig. 1).

In view of the foregoing, the rejections over at least one of Rodriguez et al., Radisch, Stevens and Chaisson are maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./

Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736